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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,858	12/04/2001	Keith D. Allen	R-690	2822
26619	7590	11/17/2004	EXAMINER	
DELTAGEN, INC.			QIAN, CELINE X	
1031 Bing Street			ART UNIT	PAPER NUMBER
San Carlos, CA 94070			1636	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/005,858	ALLEN, KEITH D.
Examiner	Art Unit	
Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 August 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 22-27 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 22-27 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 04 December 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 22-27 are pending in the application.

This Office Action is in response to the Amendment filed on 8/20/04.

### ***Response to Amendment***

The rejection to claims 22-27 under 35 U.S.C.112 1<sup>st</sup> paragraph is maintained for reasons set forth of the record mailed on 4/22/04 and further discussed below.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicant argues that the specification discloses the production of a transgenic mouse whose genome comprises a disruption in the NTTP1 gene, wherein the transgenic mouse exhibits as a result of the disruption a phenotype of anti-depressive behavior or an increase in time spent immobile while tail suspended. Applicant further argues that the specification teaches several potential uses for the claimed transgenic mouse to be used for screening drugs or putative therapeutic agents useful in modulating the anti-depressive phenotype. Applicant indicates that the claimed transgenic mouse represents a model of

antagonism of the NTTP1 gene, which results in anti-depressive behavior, thus therapeutic agents or known drugs that mimic this effect on the NTTP1 gene would be potentially efficacious in the treatment or prevention of depression. Furthermore, Applicant argue that increased immobile time exhibited during the tail suspension test is well correlated with depression, and such a mouse model is useful for characterization the role of NTTP1 gene in depression. Applicants thus conclude that one skilled in the art would know how to use the claimed transgenic mouse.

These arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement of the claimed transgenic mouse are given in detail in the previous office action. In response to Applicant's argument that the mouse can be used to screening agents that modulates anti-depressive phenotype and serve as an *in vivo* model for treating depression, Applicant is reminded that the instant specification does not provide sufficient teaching that establishes the claimed transgenic mouse as an accepted *in vivo* model for depression. The specification only teaches the claimed mouse has decreased time spent immobile while tail suspended, whereas this phenotype alone does not make the claimed mouse a valid animal model for depression. As discussed in the previous office action, Crawley et al. (1997, Psychopharmacology, Vol 132, pages 107-124) teaches that the phenotype of a mutant mouse is not only the result of the targeted gene, but it also reflects interactions with background gene, and other unknown mutations in the genetic background (see pages 107 last paragraph through page 108 1<sup>st</sup> paragraph). For example, two strains commonly used in ES cell and knockout generation C57BL/6 and various substrains of 129 are unusual on many standard behavioral paradigms. And such unique traits of 129 and C57BL/6 mice are a problem for interpretation of

behavioral phenotypes of null mutations. As such, whether the disclosed phenotype of anti-depressive behavior is result from NTTP1 gene null mutation alone is unpredictable. In addition, as discussed previously, since the function of the NTTP1 is not known in other animals, whether depression in other animals, including human is result from NTTP1 disruption is unpredictable. Furthermore, it is also unpredictable whether there is a gene corresponding to the mouse NTTP1 in other animals. Thus, without teaching from the specification, one skilled in the art would not know how to use the claimed transgenic mouse as an *in vivo* anti-depression model or use it to screen therapeutic agents that modulates depressive behavior. Therefore, the claimed mouse is not enabled by the instant specification, and this rejection is maintained.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

DAVE T. NGUYEN  
PRIMARY EXAMINER

